

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

RECD 03 APR 2001

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| Applicant's or agent's file reference 92845 | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). | |
| International Application No. PCT/AU00/01048 | International Filing Date (day/month/year) 31 August 2000 | Priority Date (day/month/year) 31 August 1999 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ C07K 14/22, 16/12; A61K 38/48, 39/095; C12N 15/31 | | |
| Applicant COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

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|---|--|
| Date of submission of the demand 5 March 2001 | Date of completion of the report 20 March 2001 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer DAVID GRIFFITHS Telephone No. (02) 6283 2628 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|---------------|-----|
| Novelty (N) | Claims 1 - 38 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1 - 38 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1 - 38 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The present invention relates to antigens of *Moraxella*: peptides related to SEQ. ID. No. 1, nucleic acids encoding them, compositions containing them and antibodies raised against them.

Novelty (N) and Inventive step (IS)

WO 90/07525 discloses a cytotoxin from *M. bovis* that is substantially free from intact microbial cells. No sequences are given for the cytotoxin.

EP 146 523 proteases which can be used as immunoprophylactic agents for protection against *M. bovis*. No sequences are given for these proteases.

Journal of Clinical Microbiology, vol. 13, No. 2, pages 269-271, discloses hydrolytic enzymes from *Moraxella bovis*".

FEMS Microbiology Letters, Vol. 124 (1994) pages 69-73 discloses a haemolytic cell-free preparation of *Moraxella bovis* which confers protection against infectious bovine keratoconjunctivitis—no sequences are disclosed.

American Journal of Veterinary Research, Vol. 51, No. 2, pages 191 - 196 discloses leukocidic and haemolytic filtrates from *Moraxella bovis*—no sequences are disclosed.

None of the citations can be fairly said to disclose or suggest the invention defined in the present claims and so they must be acknowledged as being novel and involving an inventive step.

Industrial applicability (IA)

All claims meet the criterion of industrial applicability because they define polypeptides, nucleic acids, compositions or antibodies.

PATENT COOPERATION TREATY

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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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| Applicant's or agent's file reference 92845 | <div style="display: flex; justify-content: space-between;"> <div style="text-align: center;">FOR FURTHER ACTION</div> <div style="font-size: small;">see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below</div> </div> | |
| International application No. PCT/AU00/01048 | International filing date (<i>day/month/year</i>) 31 August 2000 | (Earliest) Priority Date (<i>day/month/year</i>) 31 August 1999 |
| Applicant COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION et al | | |

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**
 - a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
 - b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished
2. ☐ Certain claims were found unsearchable (See Box I).
3. ☐ Unity of invention is lacking (See Box II).
4. With regard to the title,

☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:
5. With regard to the abstract,

☒ the text is approved as submitted by the applicant
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.
6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.
☐ because the applicant failed to suggest a figure
☐ because this figure better characterizes the invention

☒ None of the figures

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/01048

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: C07K 14/22, 16/12; A61K 38/48, 39/095; C12N 15/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

ANGIS: SEQ ID Nos. 1, 3, 5

ESPACE: keywords: Moraxella, antigen

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|-----------|--|-----------------------|
| A | WO 90/07525, A1 (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA (12 July 1990) see whole document | 1-38 |
| A | EP 0 146 523, A2 (NORDEN LABORATORIES) (26 June 1985) see whole document | 1-38 |
| A | Journal of Clinical Microbiology, vol. 13, No. 2, (February 1981), pages 269-271, Sandra K. Frank <i>et al.</i> , "Hydrolytic Enzymes of <i>Moraxella bovis</i> ". see whole document | 1-38 |

☒ Further documents are listed in the continuation of Box C
 ☒ See patent family annex

- * Special categories of cited documents:
- | | |
|---|---|
| <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier application or patent but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> | <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p> |
|---|---|

Date of the actual completion of the international search

16 October 2000

Date of mailing of the international search report

23 OCT 2000

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustalia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

DAVID GRIFFITHS

Telephone No: (02) 6283 2628

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/01048

| C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT | | |
|---|---|-----------------------|
| Category* | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
| A | FEMS Microbiology Letters, Vol. 124 (1994) pages 69-73, F. Mark Billson <i>et al.</i> , "A haemolytic cell-free preparation of <i>Moraxella bovis</i> confers protection against Infectious Bovine Keratoconjunctivitis". see whole document | 1-38 |
| A | American Journal of Veterinary Research, Vol. 51, No. 2 February 1990' pages 191-196, Patricia S. Hoiem-Dalen <i>et al.</i> , "Comparative characterization of the leukocidal and hemolytic activity of <i>Moraxella bovis</i> ". see whole document | 1-38 |

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/01048

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

| Patent Document Cited in Search Report | | | | Patent Family Member | | | |
|--|----------|----|-----------|----------------------|---------|----|--------------|
| EP | 146523 | DE | 3482442 | DK | 5950/84 | ES | 538474 |
| | | ES | 8608320 | GR | 81194 | IE | 57878 |
| | | JP | 60-146831 | NZ | 210490 | PT | 79640 |
| | | US | 4675176 | ZA | 8409616 | | |
| WO | 90/07525 | AU | 50886/90 | | | | |
| | | | | | | | END OF ANNEX |